JUN - 4 2001

K 010669

5 510(k) Summary

Submitter's Name: Thuris Corporation

Submitter's Address: 620 Newport Center Drive, Suite 1100
Newport Beach, CA 92660

Submitter's Telephone: (949) 856-9033

Contact Name: Richard Granger

Date Summary was Prepared: March 2, 2001

Trade or Proprietary Name: NeuroGraph Evoked Potential System (EPS)

Common or Usual Name: Electroencephalograph (EEG)
Evoked Potential (EP)

Classification Name: Electroencephalograph (21 CFR 882.1400)

Evoked Potential Photic Stimulator (21 CFR 882.1890)

Evoked Potential Auditory Stimulator (21 CFR 882.1900)

Predicate Devices:

Device Name	510(k) Number
Easy II EEG System	K946094
Ceegraph Netlink	~~K002970~~ K002570
SCAN LT40	K001564
Bravo Multi-Modality System	K991054
Phoenix Digital EEG	K002316

RHG 7/4/01

Description of the Device and Summary of the Technological Characteristics:

The NeuroGraph Evoked Potential System is an EEG device that records, displays and stores physiological potentials from the scalp. This system also generates the visual and audio stimuli used for the evoked responses. There are two key components to the NeuroGraph EPS, the Monitor and the Viewer. The Viewer consists of a laptop computer running software required to control, record and display EEG data collected from the Monitor.

The Monitor delivers audio and visual stimuli to a human subject wearing LED goggles and audio headphones. Surface electrodes from a third-party electrode array headset gather biopotential signals. The Monitor acquires data from 20 EEG and 1 auxiliary channels. The Monitor conditions those signals, converts them to 16-bit digital data, and transmits them to the Viewer for storage and display. The Viewer can display and store the data at a rate of 450 Hz per channel. The Monitor component of the NeuroGraph EPS consists of a molded plastic enclosure approximately 9"x 6"x 6" in size, weighing approximately 3.6 lbs. Power to the box is supplied with a medical-grade power supply. Communication to the Viewer is performed through the USB port.

The Viewer consists of a laptop computer and software to provide a graphical user interface to the Monitor. The main screen contains an image box with the live data tracings from the 21 channels. Continuous EEG may be displayed or a pre-programmed test suite of visual and auditory stimulation may be used to collect and display evoked potential signals.

Indications for Use:

The NeuroGraph Evoked Potential System (NeuroGraph EPS) is for use by qualified medical professionals and is intended to record and display electroencephalograph (EEG) and evoked potential (EP) data in private practices, clinics or hospital environments to assist in the diagnosis and monitoring of central and peripheral nervous system disorders.

Substantial Equivalence:

Like the predicate devices, the NeuroGraph EPS is designed to collect and display EEG and EP data from the subject. The NeuroGraph EPS contains the same technological characteristics as the predicate devices, including the methods for amplification, filtering, analog to digital conversion, and data storage. EEG signals are passively recorded and EP signals are evoked using a light source or sound source. The EEG or EP signals are digitized, displayed on the computer monitor, and stored on electronic media. The safety characteristics and intended use for the devices are also similar. The key differences between the NeuroGraph EPS and other predicate devices are analysis and reporting features that do not affect safety or efficacy.

Testing:

Various tests of the hardware and software to verify system specifications have been performed. A verification procedure with pass/fail criteria was developed and executed to ensure that the product met all the specified requirements. As part of this verification, a certified body has conducted tests to determine the conformance of the device to the recognized standards shown below.

UL2601
IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
IEC 60601-2-26

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2001

Richard H. Granger, Ph.D.
Chief Executive Officer
Thuris Corporation
620 Newport Center Drive, Suite 1100
Newport Beach, California 92660

Re: K010669
Trade/Device Name: NeuroGraph Evoked Potential System (EPS)
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: March 3, 2001
Received: March 6, 2001

Dear Dr. Granger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Thuris Corporation

510(k) Number (if known): K010669

Device Name: NeuroGraph Evoked Potential System (EPS)

Indications For Use:

The NeuroGraph Evoked Potential System (NeuroGraph EPS) is for use by qualified medical professionals and is intended to record and display electroencephalograph (EEG) and evoked potential (EP) data in private practices, clinics or hospital environments to assist in the diagnosis and monitoring of central and peripheral nervous system disorders.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010669

Prescription Use ✓ Over the Counter Use _____
per 21 CFR 801.109